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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,103	09/12/2003	Parminder Singh	2335-0008.22	6566
23980	7590	06/17/2005		
REED INTELLECTUAL PROPERTY LAW GROUP 1400 PAGE MILL ROAD PALO ALTO, CA 94304-1124			EXAMINER VANIK, DAVID L	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 06/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/661,103

Applicant(s)

SINGH ET AL.

Examiner

David L. Vanik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

### DETAILED ACTION

Receipt is acknowledged of the applicant's Information Disclosure Statements filed on 2/7/2005 and 12/19/2003.

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-28, 38-59 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 7-16, 21-61 of copending Application No. 10/359,548 ('548). Although the conflicting claims are not identical, they are not patentably distinct from each other because, like the instant application, co-pending application '548 teaches a composition comprising the following (Claims 1 and 55):

- 1) a water-swellaable, water-insoluble polymer,
- 2) a blend of a hydrophilic polymer with a complimentary oligomer,
- 3) an active agent or whitening agent,

4) a backing member (in the case of '548, a "release liner").

As stated above, '548 teaches a teeth whitening composition comprising a hydrogel (1-3) and a backing or release liner (4). The composition proposed by '548 can be used in a method for whitening teeth (Claims 53-61). The instant application uses the same (1) water-swelling, water-insoluble polymers, (2) blend of a hydrophilic polymer with complementary oligomers, (3) and whitening agents as set forth in the '548 claim set (Claims 1-3, 7-16, 21-40). The instant application and co-pending application '548 also use the same percentage of chemical components (see Claims 41-52 of '548). The polymer-based release liner of '548 is being interpreted as a "backing member." It should also be noted that several other references, such as US Patent 5,310,563 and 5,879,691, teach a teeth whitening system comprising a backing member. As such, teeth whitening systems comprising a teeth whitening agent and a backing member are well known in the art.

With respect to the backing member, absent a clear showing of criticality, the determination of a backing member material is within the skill of the ordinary worker as part of the process of normal optimization.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 27, 29-39, and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by US patent 5,945,457 ('457).

'457 disclose a hydrogel composition comprising a hydrophilic polymer capable of bonding to a hydrophilic polymer (column 3, lines 41-53 and column 9, lines 7-60), a water-swellaable polymer (column 8, lines 33-35), an active agent (abstract), and a polymer backbone or "backing member" (abstract). The water-swellaable polymer can be methacrylic acid (column 7, line 43), the hydrophilic polymer can be acrylic acid (column 5, line 53) or N,N dimethylaminoalkyl(meth)acrylamide (column 5, line 37). The composition can be a hydrogel (column 8, lines 33-35).

It is the examiner's position that, inherently, the composition advanced by '457 has the same decomposition characteristics as enumerated in the instant claims 29-36. Since the essential elements of the '457 composition are identical to the instant compositions (that is, a hydrogel composition comprising a hydrophilic polymer capable of bonding to a hydrophilic polymer, a water-swellaable polymer, an active agent, and a polymer backbone or "backing member"), the composition would inherently have the same physiochemical properties as the compositions set forth in the instant application. As such, it is the examiner's position that the composition advanced by '457 anticipates the compositions enumerated in the instant claim set.

Claims 37 and 38 are product-by-process claims. As such, claims 37 and 38 are treated as product claims and not as method claims. By disclosing a hydrogel composition comprising a hydrophilic polymer capable of bonding to a hydrophilic polymer, a water-swellaable polymer, an active agent, and a polymer backbone or "backing member," '457 meets the limitations of the instant claims 37-38.

The claims are therefore anticipated by 5,945,457 ('457).

Claims 1-7, 27, 29-39, 42, and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by US patent 5,719,197 ('197).

'197 disclose gel composition comprising (column 8, line 62) a hydrophilic polymer capable of bonding to a hydrophilic polymer (column 9, line 59 - column 10, line 6 and column 4, line 4), a water-swellaable polymer (column 9, line 65), an active agent (column 15, line 29), and a polymer backbone or "backing member" (column 2, lines 39-41). The compositions can be used to treat teeth (column 3, line 5). According to '197, peroxide can be used as the active agent (column 15, line 29). The fact that peroxide is used as an anti-acne agent in '197 does not detract from its use as teeth treating agent. In fact, applicant also contemplates the use of the instant composition in treating skin conditions, such as acne (see the instant specification/disclosure page 12, paragraph 0049).

It is the examiner's position that, inherently, the composition advanced by '197 has the same decomposition characteristics as set forth in the instant claims 29-36. Since the essential elements of the '197 composition are identical to the instant

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compositions (that is, a hydrogel composition comprising a hydrophilic polymer capable of bonding to a hydrophilic polymer, a water-swellaable polymer, an active agent, and a polymer backbone or "backing member"), the composition would inherently have the same physiochemical properties as the compositions as enumerated in the instant application. As such, it is the examiner's position that the composition advanced by '197 anticipates the compositions enumerated in the instant claim set.

Claims 37 and 38 are product-by-process claims. As such, claims 37 and 38 are treated as product claims and not as method claims. By disclosing a hydrogel composition comprising a hydrophilic polymer capable of bonding to a hydrophilic polymer, a water-swellaable polymer, an active agent, and a polymer backbone or "backing member," '197 meets the limitations of the instant claims 37-38.

The claims are therefore anticipated by 5,719,197 ('197).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

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3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 16-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 5,945,457 ('457) or US 5,719,197 ('197).

The teachings of both '457 and '197 are enumerated above.

Neither '457 nor '197 recite the exact percentage of chemical ingredients as set forth in the instant claims 16-26. However, it would have been within the skill of one of ordinary skill in the art at the time the invention was made to optimize the compositions advanced by either '457 or '197 based on particular use or application. Therefore, it would have been obvious given the disclosures of '457 or '197 to optimize a hydrogel composition comprising a hydrophilic polymer capable of bonding to a hydrophilic polymer, a water-swellaable polymer, an active agent, and a polymer backbone or "backing member"

### ***Correspondence***

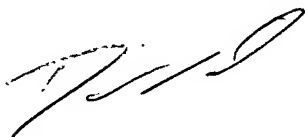
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Vanik whose telephone number is (571) 272-3104. The examiner can normally be reached on Monday-Friday 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at (571) 272-0588. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

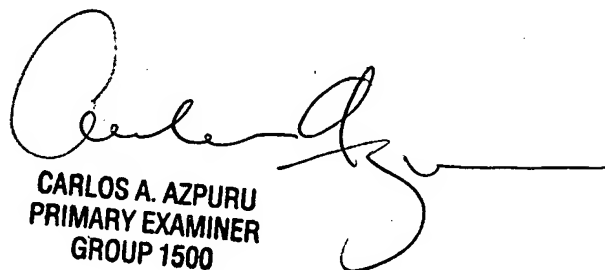
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Vanik, Ph.D.  
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6/10/05



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